STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Renée D. Coleman-Mitchell, MPH
Commissioner

Ned Lamont
Governor

Susan Bysiewicz
Lt. Governor

Healthcare Quality And Safety Branch

June 26, 2019

Andrew Agwunobi, Administrator
John Dempsey Hospital
263 Farmington Ave
Farmington, CT 06032

Dear Mr. Agwunobi:

Unannounced visits were made to John Dempsey Hospital commencing on October 15, 2018 and concluding on June 7, 2019 by a representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations, and a certification inspection.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by July 10, 2019.

The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by July 10, 2019 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

An office conference has been scheduled for August 1, 2019 at 2:00PM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain

DATES OF VISIT: Commencing on October 15, 2018 and Concluding on June 7, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

legal representation, your attorney may accompany you to this meeting. Please be prepared to discuss those violations identifed with an asterisk.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan Newton, RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:mb

Complaint #22222, 22548, 20213, 20564, 21985, 21622, 21945, 23904, 19927, 22679, 23778, 21563, 22868, 23678, 20054, 20325, 21439, 22177, 23767, 24911, 25555, 25270, 24891

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Services (1) and/or (i) General (6).

DATES OF VISIT: Commencing on October 15, 2018 and Concluding on June 7, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

1. *Based on clinical record review and interviews with staff for 1 of 3 patients (Patient #10), the hospital failed to ensure a safe environment when the patient was able to obtain and swallowed a needle. The findings include:
   a. Patient #10 was admitted to the emergency department on 8/18/17 after ingesting body spray at another healthcare facility. The patient was accompanied by 2 staff members from the other facility and was also placed on a 1 to 1 sitter. According to the clinical record the patient's ED room was cleaned for suicide precaution. Patient #10 exhibited behavioral dyscontrol on two separate occasions requiring the assistance of additional staff (code strong). During the second code strong, Patient #10 identified that he/she had swallowed a needle. An X-ray confirmed a foreign body in the esophagus which required procedural intervention to remove it. It was then identified that the foreign body was a butterfly-type needle.
   Interview with RN #1 on 11/5/18 at 10:00 AM identified that a butterfly needle was used to draw blood but a butterfly needle was not used during Patient #10's care and there were no butterfly needles in the room. RN #1 identified that he/she had established an IV line and drew blood from that line. RN #1 identified that it was not known how Patient #10 came into possession of a butterfly needle.
   Interview with MA #1 on 11/5/18 at 10:15 PM identified that he/she had been providing 1 to 1 sitter observations for Patient #10 when the patient became agitated, threatening to punch staff and pulled his/her IV out. Blood was dripping from the patient's wrist and the patient began flicking the blood at staff. At the same time, the patient identified that he/she had a needle and swallowed it. MA #1 identified that there were no butterfly needles visible in Patient #10's room.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (d) Medical records (3).

2. Based on clinical record review and interview for 1 (P#5) of 3 patients reviewed for physician follow up and evaluation the hospital failed to ensure an evaluation had been completed according to the plan of care. The findings include:
   a. Patient (P) #5 with a chief complaint of right sided pain, underwent an abdominal ultrasound which identified a mass attached to P#5's uterus and right ovary. P#5 was referred to Hospital #1 for evaluation and treatment. On 3/11/16 P#5 underwent laparoscopy and a surgical hysterectomy by MD#1. Consent for anesthesia dated 3/11/16 indicated a risk of anesthesia administration included injury to lips, teeth or dental work.
   According to a preadmission record dated 3/9/16 P#5 did not have any dental abnormalities. An Intra operative record dated 3/11/16 indicated P#5 underwent tracheal intubation which was atraumatic and no dental injury was identified. However a progress note dated 3/11/16 at 8:30 PM indicated P#5 had a small chip in his/her front left tooth which was reported by the patient. The note indicated anesthesia was called and would see P#5. In addition review of the medical record failed to indicate P#5 was seen by anesthesia for evaluation of the dental injury. Review of the medical record lacked documentation that anesthesia had evaluated P#5’s dental injury.

DATES OF VISIT: Commencing on October 15, 2018 and Concluding on June 7, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

During an interview and review of the medical record with the Chief of Anesthesia on 11/28/18 at 1:30 PM he/she indicated an anesthesia staff member is on call 24 hours a day and the Operator would page the anesthesia staff and inform him/her of the requested evaluation. The Chief of Anesthesia indicated the medical record did not contain documentation that anesthesia had evaluated P#5 and the expectation would be that the anesthesia staff would evaluate and document the patient assessment and plan.
Policy for Entries in the Medical Record indicated all patient medical record entries for services provided must be accurate and complete with evidence documented to support the diagnosis/condition, justify the care/treatment and services rendered, document the course and results of care, treatment and services, and sufficiently promote continuity of care among providers.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (e) Nursing Services (1) and/or (i) General (6).

3. Based on clinical record review, facility documentation and interviews for one of three sampled patients (Patient #4) reviewed for pain medication order and administration, the facility failed to assess the patient according to facility protocol. The findings include:
   a. Patient#4 was admitted on 4/8/16 with a diagnosis of right femur leg fracture. Past medical history included COPD, hypertension, severe osteoporosis and atrial fibrillation on Eliquis.
   The orthopedic consult dated 4/8/16 recommended open reduction internal fixation (ORIF) right femur fracture with plan for surgery 48-72 hours after last dose of Eliquis.
   The physician's orders dated 4/9/16 directed Valium tablet 5mgs every 6 hours as needed for pain, Dilaudid 0.2mg intravenous (IV) every 3 hours as needed for break through pain scale 1-3, Dilaudid 0.4mg IV every 3 hours as needed for break through pain scale 4-7 and Dilaudid 1mg IV every 3 hours as needed for break through pain scale 8-10.
   The pain assessment on 4/9/16 at 12:30AM identified a pain score of 5. The Medication Administration Record (MAR) identified Valium administered at 1:01AM.
   The nurse's progress note dated 4/9/16 at 2:34AM identified will continue to monitor, assess and update MD as necessary.
   The pain assessments score at 4:00AM identified a pain score of 5 and sedation score of 4, a subsequent pain assessment at 4:49AM identified a pain score of 9. The MAR identified Dilaudid 1mg administered at 4:49AM.
   A pain reassessment at 5:05AM identified a pain score of 2.
   The physician clinical progress note dated 4/9/16 at 9:43AM identified Patient#4 was found lethargic but arousable, vital signs stable, plan to stop narcotics due to over sedation, move to telemetry unit for monitoring and administer Narcan.
   Review of the MAR identified Narcan 0.1ml administered on 4/9/16 as ordered at 9:45AM and 9:48AM with good effect.
   Review of the clinical record failed to identify a sedation score after administration of an IV narcotic.
   Review of the medication related review form dated 4/11/16 concluded the combination of benzodiazepam and narcotics can make a patient prone to respiratory depression.
   In an interview on 10/18/18 at 11:00AM, Pharmacist#1 identified Valium effectiveness

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

peaks between 15 minutes to 2 hours therefore if administered at 1:00AM there is the potential for it to still be in the patient's system.
In an interview and clinical record review on 10/18/18 at 3:00PM, the internal medicine physician (MD#8) identified a number of factors are considered when placing a narcotic order i.e. should typically start at a low dose and titrate up as necessary. In addition when administering a narcotic the pain score, the patient's naivety to narcotic and age should be taken into account.
Review of the facility protocol for 'Pain: care of the patient' identified in part patients who have received IV narcotics must also have respiratory rate and sedation assessed. In addition, the RN will identify patient specific factors influencing response such as prior exposure to opioids (naivety or tolerance), age, renal and liver function, pain severity and co-morbidities.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (6).

4. *Based on observations on the behavioral health unit, facility documentation and clinical record review, the facility failed to provide care in a safe setting on the psychiatric unit when it was identified that sleeping rooms and units were not maintained in such a manner to promote the safety and well-being of patients. The findings include:
Observations during a tour of the psychiatric unit on 10/16/18 at 1:40PM identified multiple ligature points that included the following:
   a. 18 patient beds were not designed to a psychiatric/institutional standard and had identified ligature points, i.e.: metal frames, wooden head and footboards and plastic head and foot boards with holes in them
   patient bed room doors were noted with exposed door hinges
   bedroom doors were identified with 3 different types of door knobs/handles that were ligature points
   "no-entry" tubular metal swing gates between the nurse's station and common hallways had large openings
   Interview with the Compliance Officer on 10/16/18 at 2:15PM stated that the facility had conducted a risk assessment (updated on 9/28/18) prior to the survey. An action plan to remove the ligature risks was developed and the facility was in the process of completing components of the plan.
   Interview with the Unit Manager on 10/16/18 at 2:10PM stated that environmental rounds are conducted every shift and that all patients are monitored at least every 15 minutes.
   Review of the psychiatric unit environmental rounds documentation failed to include observations of the door hinges, non-psychiatric designed beds, curtains or door knobs. The unit census on 10/16/18 was 17. There were no patient's with current suicidal ideation or self-harm tendencies.
   Subsequent to surveyor inquiry an action plan was submitted that indicated the following:
   a. Implementation of education to all staff on ligature risks in the environment,

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

addition of environmental rounding every 15 minutes, patient suicidal risk assessments on admission and every shift while awake, and provision of 1 to 1 or constant observation as deemed necessary.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing Service (1).

5. Based on clinical record review, interview and policy review, for one of three patients' reviewed for care and services (Patient #16), the hospital failed to ensure that oxygen was administered based on a physician's order/protocol and/or that nursing assessments were documented. The findings include the following:
   a. Patient #16 presented to the emergency room (ED) on 11/20/16 at 9:48 PM for evaluation of shortness of breath. The patient had a history of ALS and reported tongue paralysis. The nursing note dated 11/20/16 at 10:26 PM indicated that the patient was alert and oriented, had labored breathing, was tachypneic, had rhonchi in the left upper lobe and right upper lobe, and had an oxygen saturation of 92% on 2 liters of Oxygen. Review of the record on 10/18/18 at 2:30 PM with the ED Manager indicated that at 12:00 AM on 11/21/16 the patient was on 2 liters and had a saturation of 95% and at 1:51 AM, had an oxygen saturation of 96% on 4 liters of oxygen. The record failed to reflect an assessment, rationale and/or physician's order for the change of oxygen from 2 liters to 4 liters. Review of the Oxygen policy indicated that the flow rate should be adjusted based on a medical order.

      Review of Patient #16's clinical record identified that the patient received Ativan 1 mg IV on 11/21/16 at 12:40 AM absent an assessment to determine the efficacy of the medication. The medication administration record indicated that the patient received an additional 1 mg of Ativan IV on 11/21/16 at 1:23 AM, however, failed to reflect an assessment post administration to determine efficacy of the medication. Review of the Medication policy indicated that the 8 rights of medication of administration will be followed, in part the right reason and right response to a medication.

      Review of Patient #16's record indicated that a code was called on 11/21/16 at 2:25 AM. The nurse's note dated 11/21/16 at 3:17 AM indicated that the patient arrived to the floor accompanied by the emergency room RN with the HOB in fowler's position (semi-upright) during transfer. The patient was transferred with assist of 4 staff and vital signs were obtained while ED RN giving report. The patient was nonresponsive and moaning upon admission to the floor, was unable to obtain an initial oxygen saturation, and respiratory therapy was called. The patient became cyanotic, without respirations or pulse and a code blue was called with CPR initiated at 2:25 AM. Review of the clinical record failed to identify assessments and/or interventions taken by nursing when the patient had a change in condition. Review of the Change of Condition policy indicated staff should document in the medical record the nursing assessment and findings, actions taken, and /or the patient's response.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2) and/or (4) and/or (d) Medical Records (3) and/or (e)

DATES OF VISIT: Commencing on October 15, 2018 and Concluding on June 7, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Nursing service (1) and/or (g) Pharmacy (1) and/or (i) General (6).

6. *Based on a review of clinical records, interview, and policy review for one of three patients' reviewed for the Vancomycin pharmacy protocol (Patient #17), the hospital failed to ensure that the attending physician was notified of an elevated laboratory value prior to the patients discharge. The finding includes the following:
   a. Patient #17 presented 7/14/18 with a history of microcytic hypochromic anemia and hidradenitis suppurativa. The Physician's note indicated that the patient had significant tense swelling of the right buttock with multiple areas of purulent drainage and cellulitis around the area. The record indicated that on 7/14/18 the patient had a BUN of 6 (normal 8-24) and creatinine of 0.7 (normal 0.6-1.2).
   On 7/15/18, the patient was taken to the operating room for incision and drainage (I&D) of the right buttocks, returned to the medical floor, and had Vancomycin 2000 mg prescribed every 12 hours empirically for cellulitis.
   The pharmacist note dated 7/16/18 at 12:45 PM indicated that that patient's creatinine bumped up to 3.5 and the Vancomycin trough was 65 (target 10-20 mg/l), the dose hanging was stopped and the physician was informed of the elevated trough.
   Interview with MD #9 on 10/19/18 at 1:15 PM indicated that at the time of discharge he was not aware of the patient's elevated creatinine and/or that a creatinine level had even been ordered. MD #9 indicated that the day after discharge the attending physician notified him of the elevated creatinine and the patient was called and directed to an outpatient lab for further studies. The patient's subsequent creatinine was 7.7 and the patient was readmitted to the hospital on 7/18/18 and subsequently required 2 hemodialysis treatments.
   Interview with Pharmacist # 1 on 10/19/18 at 10:00 AM indicated that lab work was ordered as part of a pharmacy protocol initiated for patients on Vancomycin. Subsequent to this incident, the pharmacists will monitor the lab data daily for the patients on the protocol and notify the physician directly of any abnormal lab values.
   Review of the Discharge Policy indicated that the discharge process shall be integrated and coordinated by healthcare professionals, ensure quality coordinated continuity of care.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).

7. *Based on clinical record review, interview and policy review for 1 of 3 patients reviewed for obtaining and delivery of surgical specimens (Patient #1) the facility failed to ensure that surgical staff followed the policy for obtaining specimens. The finding includes the following:
   a. Patient #1 presented to the surgical center on 3/19/19 for an elective hysteroscopy, dilation and curettage of uterus for diagnostic purposes for suspected endometrial hyperplasia. The operative note dated 3/13/19 at 12:03 PM indicated that endometrial curetting's and a small polyp were obtained by MD#1 at 11:33 AM. Review of the laboratory report dated 3/19/19 at 10:27 AM identified that no specimen was identified after processing. The note indicated that the container was labeled and clearly marked "endometrium curetting's and

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

polyp" but no soft tissue was identified. The Pathology Assistant and Pathologist double checked the container, the formalin was filtered and cassette was submitted for possible microscopic tissues.
Interview with the Scrub Tech on 5/13/19 at 9:30 AM indicated that the specimen was obtained, and was on a telfa sponge. The Scrub Tech indicated that he verified the label on the container at the same time RN #1 stated what the specimen was and he then dropped the specimen into the container. The Scrub Tech stated he could not verify the specimen went into the container because as he dropped the specimen in he turned back to the patient.
Interview with RN #1 on 5/9/19 at 11:40 AM and 2:30 PM indicated that the specimen is normally on a telfa sponge and then placed in the specimen container. RN #1 indicated that he cannot verify that he saw the specimen in the container.
Interview with the Pathology Assistant on 5/9/19 at 12:30 PM indicated that when she opened the container she was unable to visualize any tissue. Pathology Assistant #1 had the Pathologist verify this and indicated that when she received the specimen she had a feeling it was empty due to the fact that the formalin was clear. The Pathology Assistant indicated that in 95% of similar cases the formalin will turn red, due to blood on the telfa.
Review of the policy for Specimen, Pathology: Care and Handling indicated that the scrub person and the circulating nurse should verify the correct label and the specimen match completely when labeling each specimen. The policy indicated that the labeled containers should be checked to verify they contain specimens prior to delivery to the laboratory.

The following is a violation of the Regulations of Connecticut State Agencies Section Sec. 19a-127n.

8. Based on interview and policy review the facility failed to ensure that an adverse event was reported in a timely manner. The finding includes the following:
   a. Patient #1 presented to the surgical center on 3/19/19 for an elective hysteroscopy, dilation and curettage of uterus for diagnostic purposes for suspected endometrial hyperplasia. The operative note dated 3/13/19 at 12:03 PM indicated that endometrial curetting's and a small polyp were obtained by MD#1 at 11:33 AM on 3/13/19. Review of the lab report dated 3/19/19 at 10:27 AM identified that no specimen was identified after processing. The note indicated that the container was labeled and clearly marked "endometrium curetting's and polyp" but no soft tissue identified. The Pathology Assistant and pathologist double checked the container, formalin was filtered and cassette submitted for possible microscopic tissues.
   Interview with the Pathology Assistant on 5/9/19 at 12:30 PM indicated that when she opened the container she was unable to visualize any tissue. PA #1 had the pathologist verify this and indicated that when she received the specimen she had a feeling it was empty sue to the fact that the formalin was clear. The PA indicated that in 95% of similar cases the formalin will turn red.
   Review of facility documentation indicated that the adverse event was reported to the Quality Department on 4/8/19. Interview with the Director of Regulatory indicated that her department was notified of the incident and further information was gathered resulting in a late submission.
   Review of the facility policy Incident Reporting indicated that staff should report any

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

deviation for the normal or expected outcome pf a process. Any provider or staff member who discovers, witnesses or becomes aware of an occurrence should immediately report the occurrence to the Clinical Risk Manger or the Director of Regulatory Compliance.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2) (B) and/or (4) (A) and/or (d) Medical records (3) and/or (i) General (6).

9. *Based on a review of clinical records, facility documentation, interviews, and policy review for one of four patients who had total shoulder replacements, (Patient #25), the hospital failed to maintain an accurate accounting of all instruments utilized intraoperatively resulting in an unintended retained foreign body. The finding includes:
   a. Patient #25 was admitted on 8/25/17 for a total right shoulder replacement (glenoid and proximal humerus) due to osteoarthritis. Review of the nursing intraoperative record dated 8/25/17 identified that a time out was conducted and surgery commenced at 8:00 AM. Review of the operative report dated 8/25/17 identified in part, that the glenoid peg drilling guide was inserted, each of the three (3) holes were drilled 1st by drilling a hole and inserting a metallic peg. Once all three (3) drill holes were created, the drilling guide and the pegs were removed. The patient tolerated the procedure well, sponge and needle counts were correct times two. Review of the nursing intraoperative record identified that the final closing count for instruments, sharps, sponges, and small items, were documented as correct by a scrub technician and the circulating registered nurse, and surgery concluded at 9:45 AM.
   Review of the clinical record identified that the patient was discharged home on 8/26/17. Review of a right shoulder x-ray dated 8/28/17 identified a metallic peg was seen in the axillary pouch. Review of hospital documentation dated 9/22/17 noted that MD #35 believed the object was a peg from the surgery, was in position, posed no risk to the patient, didn't feel surgical removal was necessary, and would monitor the patient.
   Review of the clinical record and interview with the OR Nurse Manager on 11/27/18 at 2:00 PM stated that the three (3) pegs used for this surgery were part of total shoulder kit and the pegs were not included in the counts, however, the Scrub Technician is accountable to review the table and the expectation is when something is handed up, something is handed back. Subsequent to this incident, staff were educated to count the three (3) pegs and document under "other" on the count worksheets.
   Review of the operative record dated 8/25/17 and interview with Surgical Technician #1 on 11/27/18 at 3:00 PM identified he was precepting another surgical technician during this case and they had both transferred instruments to the surgeon. Surgical Technician #1 stated the three pegs used for this surgery were not part of the count during this period of time and although he tries to make a mental note, or write on the table instruments passed, it was an oversight that three pegs were not returned back for an accurate accounting.
   Interview with MD #35 (orthopedic surgeon) on 11/28/18 at 12 noon stated he handed the pegs to the scrub technician when removed from the surgical site and he relies on the scrub technician to tell him the counts are correct at the end of the case. MD #35 felt that one of the pegs fell out of the metal guide and into the wound then was not accounted for.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Subsequent to this case, MD #35 stated he ensures all pegs are counted.
Review of the Protocol for Counts: Prevention of Retained Surgical Items directed that other miscellaneous items that are opened onto the sterile field should be accounted for during all procedures for which miscellaneous items are used.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2) (B) and/or (4) (A) and/or (d) Medical records (3) and/or (i) General (6) and/or Connecticut General Statutes 19a-127n.

10. *Based on a review of clinical records, facility documentation, interviews, and policy review for one of four patients who required chest tube insertion (Patient #26), the hospital failed to ensure the catheter was inspected upon removal and sequestered when noted that the tip was retained in the patient's chest, and/or that the adverse event was reported to the Department of Public Health (DPH) in a timely manner. The findings include:

a. Patient #26 presented to the ED on 9/12/16 with complaints of shortness of breath and chest pain. The patient was noted to have a pneumothorax on the right side and had a pigtail catheter placed in interventional radiology for reexpansion of his/her lung. The patient was then admitted to the hospital for pain medication and incentive spirometer. Review of Physician Assistant (PA) #1's note dated 9/13/16 at 11:50 AM identified that the right chest pigtail was removed, occlusive dressing was applied, the patient tolerated the procedure well, post pull chest x-ray at 4PM. The note failed to identify the integrity of the catheter upon removal.
Review of the chest x-ray dated 9/13/16 at 4:15 PM identified the right-sided pleural catheter was removed and the pneumothorax has not reoccurred. A six (6) millimeter (mm) radiopaque density projecting over the right mid lung field which presumably is external was noted. A subsequent chest x-ray on 9/13/16 at 6:52 PM re-identified an approximate 7 mm tubular density overlying the right upper lobe.
Review of PA #1's note dated 9/13/16 at 7:29 PM identified that the post pull x-ray noted foreign body, tip of most recently removed pigtail catheter. Catheter inspected and distal tip portion missing. Plan was to perform video-assisted thoracoscopic (VATS) for pleurodesis and retrieve fragment during surgery (pleurodesis was planned regardless).
Review of the post-procedure note dated 9/14/16 identified that during the right VATS procedure for pleurodesis, a 2 centimeter tip (approximate size) of a pigtail catheter lodged in the chest wall was removed with no complications.
Review of the surgical pathology report dated 9/14/16 identified a foreign body from right chest cavity revealed a blue plastic tubular structure measuring 1.3 cm by 0.3 cm.
Record review and interview with Physician Assistant #1 on 11/28/18 at 11 AM stated that he did not inspect the pigtail catheter upon removal, however, did inspect the catheter once notified of the foreign body (the catheter was in the dirty utility room) on x-ray and observed that the tip of the catheter was missing. PA #1 stated the tip of the catheter is harder than the rest of the catheter and believed that the catheter stretched and the tip remained. PA #1 notified the supervising physician and interventional radiology who placed the catheter, however, failed to sequester the catheter. PA#1 further identified that the patient was scheduled for a VATS procedure that day so the tip was removed then.
Interview with the Director of Quality on 11/28/18 at 2:30 PM stated the hospital investigation

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

identified that PA #1 should have inspected the catheter when removed and sequestered the catheter when noted to have the tip missing.
Interview with MD #100 on 11/28/18 at 2:00 PM stated it is a standard of practice to inspect a catheter before placement and upon removal.
Review of the Records Management policy directed in part, that all patient medical entries for services provided must be complete with evidence documented to support diagnosis/condition, justify the care/treatment and services rendered.
Review of the adverse event reporting form identified that Patient #26 was involved in a category 1D event, (unintended retention of a foreign body in a patient after surgery or other invasive procedure) on 9/13/16, however, the event was not reported to the hospital's Risk Department until 10/7/16 at 11:13 PM then subsequently to DPH on 10/12/16. Review of this report and interview with the Director of Quality on 11/28/18 at 2:30 PM stated staff failed to report the event timely so she initiated the report to DPH once known. The Director further stated that the initial report should have been reported to DPH within seven (7) days followed by a thirty (30) day corrective action plan. Subsequently staff were reeducated on the reporting guidelines for adverse events. Review of the adverse event policy identified that an adverse event should be reported immediately and a patient safety report should be filed by the end of the shift by the person reporting the occurrence. To comply with Connecticut State Law, all adverse events that fall within the CT adverse event reporting law will be reported to DPH within the required time frame.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2) (B).

11. Based on clinical record review and interview for 1 of 10 patients (P#1) who underwent a surgical procedure, the hospital failed to ensure medical staff accountability for the quality of medical care provided to patients when the patient was not provided with appropriate discharge instructions. The finding includes:
    a. Patient (P) #1 had undergone a Transurethral Resection of the Prostate (TURP) on 9/10/18, performed by Medical Doctor (MD) #1. Review of hospital discharge education information dated 9/11/18 identified P#1 received educational information and instructions for Benign Prostatic Hyperplasia (BPH) however the medical record lacked educational material related to postoperative restrictions following a TURP.
    On 10/1/18 at 8:46 PM, P#1 arrived in the Emergency Department (ED) of Hospital #1 with a chief complaint of bleeding/hematuria starting around 4:15 PM after lifting a heavy object.
    During an interview with Compliance Officer #1 on 2/7/19 at 10:00 AM he/she indicated P#1's medical record contained discharge instructions however they were not specific to post-operative TURP.
    According to a statement by MD#1, he/she discusses postoperative activity as a routine part of counseling. He/she indicated usually there is an order for no lifting anything heavy for 1 to 3 weeks. In addition MD#1 indicated a discharge education handout is provided to the

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

patient upon discharge by either the Residents or floor nurses and he/she was not sure this had been provided.

Review of the hospital written discharge information for care after a TURP indicated the patient was to avoid lifting anything heavier than 10 pounds for 3 weeks after the procedure unless instructed otherwise by the healthcare provider.

The Discharge Planning policy indicated the RN in collaboration with other team members will instruct patients, families, significant others and designated care givers in accordance with assessment of their learning needs. Sources of education include hospital approved patient education resources and other instructional information packets.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2) (B) and/or (e) Nursing Service (1) and/or (i) General (6).

12. *Based on clinical record review, facility documentation review, and interviews for one of eleven patients' who underwent cardiothoracic surgery, (Patient #12), the hospital failed to ensure that life sustaining equipment was operated correctly. The finding includes:
    a. P#12 underwent bioprosthetic aortic valve (AV) replacement on 2/8/19 due to severe symptomatic aortic stenosis (AS). Comorbidities included hypertension and congestive heart failure.

    According to the Operative report dated 2/8/19 at 8:24 AM, during the beginning stage of the procedure when P#12 was connected to the cardiac coronary bypass machine, all cannulas were de-aired and connected to the bypass circuit. During the dissection of the ascending aorta from the main pulmonary artery, air was sucked into the heart (air embolization). Corrective interventions were implemented and replacement of the aortic valve commensed. The operative report identified the complication which occurred as intra-cardiac air during bypass surgery. After the surgery, P#12 was transferred to the intensive care unit (ICU) and was hemodynamically stable.

    According to the discharge summary dated 2/10/19 at 12:45 PM, postoperatively P#12 was unresponsive when off sedation. A stat head CT scan revealed tiny locules of air. An EEG showed no cortical activity. On 2/9/19 P#12's family requested that P#12 receive comfort care and hospice. P#12 was terminally extubated and pronounced expired on 2/10/19 at 12:45 PM.

    During an interview with Perfusionist #1 on 2/14/19 at 12:45 PM, he/she indicated that on 2/8/19 the roller head/raceway (part of the pump that pulls blood directionally through the tubing) was set up and all checks were in place prior to the start of the procedure. When the procedure started, Perfusionist #1 (primary) placed the tubing with the VRV valve (safety valve that keeps tissue at end of tubing from collapsing and allows directional flow of fluids between the raceway and the reservoir/oxygenator) onto the machine and connected with the tubing the surgeon had handed him/her, which was placed to drain the heart. However the VRV valve in the tubing was connected to the roller head/raceway pump between the roller head and reservoir in error. TheVRV valve should have been placed between the roller head/raceway pump and the patient. When blood began flowing through the tubing the VRV valve did as intended and pressurized, squirting blood out of the valve therefore

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Perfusionist #1 thought the cause of the VRV valve release was that the tubing flowing through the roller head/raceway pump was placed wrong not that the VRV valve location was wrong. The pump was turned off and Perfusionist #1 flipped over and reinserted the tubing within the roller head/raceway. The machine was turned back on and the surgeon asked if Perfusionist #1 was getting air down the venous line. It was at that time Perfusionist #1 realized and identified the error in the VRV valve placement.

On 2/15/19 at 10:30 AM, the Clinical Coordinator demonstrated the proper placement of tubing on the cardiac coronary bypass machine versus how the actual tubing was placed during P#12's surgery. It was subsequently identified that at the start of P#12's procedure, just prior to being placed on cardiac coronary bypass, the tubing containing the VRV valve was placed on the wrong side of the roller head/raceway. Perfusionist #1 did not realize that the VRV valve was in the wrong place at that time therefore he/she flipped the tubing within the roller head/raceway thinking the error was in the tubing running through the roller head/raceway.

Medical Doctor (MD) was not available for interview during the onsite investigation timeframe. During an arranged interview with MD#3 on 2/20/19 at 2:40 PM, MD#3 indicated he/she became aware of a problem when he/she heard what sounded like air coming from the vicinity of the operative field. MD#3 noted air in the circuit tubing and asked Perfusionist #1 if he/she was getting air. Perfusionist #1 did not immediately respond therefore MD#3 asked anesthesia staff to check the heart and anesthesia responded that there was air in the heart. MD#3 responded by clamping the ascending aorta to prevent air from further entering the heart. MD#3 indicated when he/she asked Perfusionist #1 what occurred Perfusionist #1 had indicated one of the one-way valves in the circuit was in the wrong location.

During an interview with Perfusionist #2 (Director of Perfusion Services) on 2/14/19 he/she indicated during P#12's surgery on 2/8/19 the VRV value was placed in the wrong position causing blood to spurt out the valve. When the blood spurted out of the VRV valve Perfusionist #1 stopped the roller head, thinking the tubing was in backwards. Perfusionist #1 then reversed the tubing in the roller head causing the flow in the line to be in the wrong direction. Perfusionist #2 indicated prior to the incident hospital practice is for 2 Perfusionist in the OR during the surgery unless circumstances do not allow. The role of the second Perfusionist is to obtain additional equipment in the room and assist with vital signs and documentation. He/she indicated since the incident 2 Perfusionist are scheduled for the surgery during initiation of cardiopulmonary bypass.

According to the Clinical Perfusionist job description the Perfusionist is responsible for the selection, setup and operation of circulation equipment during any medical situation when it temporarily and artificially replaces the patient's cardiopulmonary/circulatory functions. In addition the Perfusionist should have in-depth knowledge of extracorporeal equipment. Review of the Perfusionist job description failed to identify the number of Perfusionist assigned when bypass is used and/or distinguish the roles of each Perfusionist.

Subsequent to this incident, the hospital instituted immediate corrective measures that included:

1. The bypass machine was immediately sequestered.
2. All perfusionists were notified of the event and educated to prevent reoccurance.

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

3. Primary perfusionist for 2/8 AVR case was placed on administrative leave.
4. All elective open heart surgery cases were placed on hold.
5. All cardiothoracic surgeries that require a left ventricle vent must have the aorta cross-clamped prior to placement of the vent. Air embolism protocol will be reviewed by surgeons.
6. Any change in direction of flow or manipulation of the pump tubing after initial test will require a repeat testing of the circuit.
7. VRV valve marker (identifies directional flow) was added to roller head cover on heart lung machine at initiation of the surgery and removed upon completion.
8. A hard stop will occur when there is any alteration in the field lines and confirmation of fluid path prior to re-initiation of flow will be established.

Future measures include:

1. Two perfusionists will be in attendance at start of case through initiation of cardiopulmonary bypass.
2. Both perfusionists will independently complete the checklist on a separate form.
3. The perfusion checklist and case summary (HCH922) will be revised to include a check that the pump tubing has the VRV valve correctly placed in the set-up.
4. Each heart lung machine to receive additional roller head for independent control of field vent / suction lines.
5. Third field vent / suction line ("blue line") to be added to custom perfusion pack by manufacturer.

The following are violations of the Regulation of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).

13. *Based on clinical record reviews and interviews for three (3) of eleven (11) patients who presented to the Emergency Department (ED) for care and treatment, (Patient #1, #3, and #8) the hospital failed to ensure that the patients were assessed in a timely manner to include an Emergency Severity Index (ESI) level, vital signs and/or pain assessment during the triage process and failed to ensure that ED policies and protocols for the triage of patients was adequate to ensure timely assessment and treatment. The findings include:
    a. Patient (P) #1 had undergone a Transurethral Resection of the Prostate (TURP) on 9/10/18, performed by Medical Doctor (MD) #1. On 10/1/18 at 8:46 PM P#1 arrived in the Emergency Department (ED) with a chief complaint of bleeding/hematuria starting around 4:15 PM after lifting a heavy object. A triage nurse's note by Registered Nurse (RN) #1 dated 10/1/18 at 8:47 PM indicated P#1 reported he had a TURP procedure 3 weeks earlier. Since 4:00 PM P#1 had been passing blood and clots (from the urethra) and had difficulty urinating.

    Review of the medical record failed to identify that the patient was traiged in accordance with the Emergency Severity Index (ESI) level (1 most urgent/5 least urgent). The record failed to indicate that the patient's vital signs and/or level of pain were obtained or assessed. According to a nurse's note dated 10/1/18 at 9:23 PM, a urology practitioner called the ED requesting P#1 to be seen. The practitioner was made aware of high volume and extremely high acuity in the department at that time. The practitioner verbalized understanding. On

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

10/1/18 at 9:38 PM (52 minutes after arrival) P#1 left the hospital without being seen prior to triage and that procedure and treatment not carried out due to patient leaving prior to being seen by health care provider. P#1 indicated he/she was going to another hospital for care.

During an interview with RN#1 on 2/13/19 at 11:10 AM, he/she indicated when P#1 arrived to the ED, P#1 appeared slightly uncomfortable, was alert and oriented, stable ambulating, had good color and had driven him/herself to the ED. RN#1 indicated he/she reviewed P#1's symptoms and explained that the ED had a high acuity and critical patients and that P#1 would be seen as soon as possible, but to let RN#1 know if anything changed. RN#1 indicated at the time of P#1's ED encounter, the policy was not to do initial vital signs "up front" but rather as a nursing judgment call (when to do the vital signs) which could be once the patient gets placed in an ED room. RN#1 indicated that P#1 came to the triage desk several times (no more than 3) after using the restroom and RN #1's quick visual assessment indicated that P#1's condition had not changed. RN#1 indicated he/she had received a call from MD#2 inquiring as to when P#1 would be seen. RN#1 explained the acuity/volume of patients in the ED and his/her initial assessment of P#1. RN#1 indicated MD#1 did not indicate P#1 needed to be seen sooner. RN#1 indicated he/she had called back to the treatment area of the ED and briefly spoke with the charge nurse who was managing 2 cardiac arrests, a stroke alert and full rooms. The charge nurse indicated as soon as things settled and they could rearrange things, patients would be moved from the waiting area to a room.

During an interview with Medical Doctor (MD) #1 on 2/7/19 at 10:50 AM he/she indicated bleeding 3 weeks post operatively is not unusual however most cases resolve after continuous bladder irrigation and there is a small percentage that require going to the Operating Room (OR) for cautery. MD#1 indicated it was very rare that a patient would lose a life threatening amount of blood through the urinary tract.

During an interview with MD#2 on 2/7/19 he/she indicated P#1 had called the urology service twice post operatively. The first time MD#2 spoke with P#1 based on the symptoms P#1 had reported he/she instructed P#1 on some interventions to attempt to stop the bleeding and then be evaluated by MD#1 the next day. MD#2 indicated he/she told P#1 if he/she continued to have concerns P#1 should seek further evaluation. MD#2 indicated when P#1 called the second time that evening based on what P#1 reported and his/her level of alertness and sound on the phone, MD#2 did not feel P#1's situation was critical. However P#1 seemed more upset about having to wait in the ED to be evaluated. MD#2 then called and spoke to the triage nurse in the ED to see if he/she could expedite P#1 being seen. However the triage RN explained the acuity and volume of patients in the ED and indicated P#1 would be seen as soon as possible.

During an interview with the ED Manager on 2/6/19 at 9:40 AM he/she indicated that in discussing the events of 10/1/18 with the Charge Nurse, it was felt that staffing was adequate. The issue was that there were no available rooms due to multiple emergent cases in the ED at that time. Once the emergent cases were attended to and were less critical, staff would reassess the situation. The ED manager identified that he/she was aware of the process should he/she need additional staff.

During review of the medical records for P#1 with the ED Manager on 2/13/19 at 12:45 PM

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

he/she indicated although the ED treatment area was full, vital signs and an ESI level should have been obtained in the triage area and documented as indicated in the triage policy and nursing protocol for ED nursing assessment and documentation. The ED Manager indicated that the triage policy is in the process of revision to include that vital signs need to be done immediately in triage.

Review of the "Triage of Patients Presenting in the Emergency Department" policy directed that all patients presenting to the ED would be triaged and have an intake note documented by the RN. The ESI triage system would be used to categorize the patients based on severity and resource needs. ESI triage algorithm indicated in order to establish an ESI triage level, a patients cognitive orientation, pain/distress, heart rate, respiratory rate and oxygen level needs to be assesed. The policy indicated all ED patients would receive prompt emergency care according to their urgency level. After the initial intake, Patients with an ESI of 1, 2 or 3 (resuscitation, emergent and urgent) would be placed into appropriate ED treatment rooms so that emergency measures can be initiated immediately. Patients with an ESI of 4 or 5 (less urgent/non-urgent) would be placed in an up-front provider room where care can be provided, which includes vital signs.

A nursing protocol for ED nursing assessment and documentation identified to assess the patient and assign an acuity level and complete the triage process by obtaining in part, vital signs and a pain assessment. However, the protocol failed to identify when staff should be expected to complete the triage process.

The purpose of triage in the emergency department (ED) is to prioritize incoming patients and to identify those who cannot wait to be seen. The triage nurse performs a brief, focused assessment and assigns the patient a triage acuity level, which is a proxy measure of how long an individual patient can safely wait for a medical screening examination and treatment.

b. P#3 arrived in the ED on 10/1/18 at 7:51 PM with a chief complaint of back pain after a fall at home. At 7:51 PM, RN #1 designated that the patient was an ESI level 3, was placed in a room at 8:09 PM, and evaluated by the Physician Assistant (PA) at 11:51PM. An assessment by the PA indicated as of 11:51 PM (4 hours after arrival) no vital signs were documented. A nurse's note dated 10/2/18 at 12:33 AM indicated P#3 signed the required documentation and left Hospital #1 against medical advice (AMA).

c. P#8 arrived in the ED on 10/1/18 at 8:06 PM with a chief complaint of hypertension. Review of RN #1's nurse's note dated 10/1/18 at 8:07 PM indicated P#1 reported a high blood pressure at home and that he/she had not felt well since his/her medication had been changed. P#8 reported his/her systolic BP had been >100. Review of the medical record failed to identify vital signs or an ESI level had been obtained/documented until 9:25 PM. P#8 was placed in a room at 9:27 PM (1 hour 18 minutes after arrival) and left without further evaluation at 9:30 PM.

During an interview with the ED Manager on 2/6/19 at 9:40 AM he/she indicated ideally vital signs should be obtained right away however if there was a line, the vital signs might not be taken right away and the patient would subsequently be called back to triage as soon as possible to have vital signs obtained.

During review of the medical records for P#3 and P#8 with the ED Manager on 2/13/19 at 12:45 PM he/she indicated if P#3 was triaged at 7:51 PM, it was unacceptable that as of

DATES OF VISIT: Commencing on October 15, 2018 and Concluding on June 7, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

11:51 PM no vital signs had been obtained and documented. In addition if P#8, with a reported history of hypertension arrived to the ED at 8:06 PM complaining of a headache, vital signs and an ESI level should have been obtained and documented.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (i) General (6).

14. Based on clinical record review, policies review, review of personnel files and interview for 1 of 7 (RN#200) staff nurses who float to the Emergency Department (ED) the facility failed to ensure the staff maintained current CPI competency. The findings include:
    a. On 6/4/19 Patient (P) #100 arrived to ED with police on a Police Emergency Evaluation Request (PEER) with suicidal ideation. While being escorted to the bathroom to change the patient "bolted" from the ED.
    During a review of the incident with Compliance Specialist #1 on 6/7/19 at 2:15 PM it was identified that Registered Nurse (RN) #200's CPI (nonviolent crisis intervention training) had expired on 9/22/16 and had not been renewed as of 6/7/19. According to Compliance Specialist #1 RN#200 worked on another unit. RN#200 had been oriented to work in the ED, concluding at the end of 2018, however her CPI had expired and should have been renewed. Hospital policy for Required Certification/Training indicated all designated hospital personnel involved in direct patient care in the ED and those in job categories who float to those areas will obtain CPI certification within 3 months of employment.

DATES OF VISIT: Commencing on October 15, 2018 and Concluding on June 7, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED